



BISPHENOL A OVERVIEW

Regulatory bodies around the world have assessed the science on bisphenol A (BPA) and have determined that BPA is safe in its current uses. Based on these assessments and the potential adverse impacts on American jobs and the economy, a ban is unwarranted.

1. Government Agencies Worldwide Conclude That BPA is Safe for Use in Food Contact Products

“With regard to BPA generally, based on all available evidence, the consensus of regulatory agencies in the United States, Canada, Europe, and Japan is that the current levels of exposure to BPA through food packaging do not pose an immediate health risk to the general population, including infants and young children.” (FDA Feb. 9, 2009 Press Release – FDA Regulatory Meeting with Manufacturers and Users of BPA-Containing Materials)

- Eleven regulatory bodies around the world have recently assessed the science on BPA and have determined that BPA is safe for use in food contact products.
 - U.S. Food and Drug Administration (August 2008, February 2009)
 - European Food Safety Authority (January 2007, July 2008, October 2008)
 - European Commission Risk Assessment (June 2008)
 - Swiss Federal Office of Public Health (February 2009)
 - French Food Safety Authority (November 2008)
 - Dutch Food and Consumer Product Safety Authority (November 2008)
 - Danish Environmental Protection Agency (October 2008)
 - German Federal Institute for Risk Assessment (September 2008)
 - Food Standards Australia and New Zealand (March 2009)
 - Japanese National Institute of Advanced Industrial Science and Technology (November 2005)
 - Health Canada (October 2008, July 2009)
 - A 2008 proposal to ban polycarbonate baby bottles in Canada was based on precaution; the Canadian scientific assessment concluded that exposure is below levels that pose a risk
- In July 2009 a panel of independent scientific experts convened by the California EPA’s Office of Environmental Health Hazard Assessment unanimously concluded that bisphenol A should not be listed as a reproductive or developmental toxicant under California’s Proposition 65 law.
- Existing food safety programs are already precautionary - they employ safety factors to create a margin of safety between public exposure and levels found to cause effects in laboratory animals.

The European Food Safety Authority (EFSA) set a Tolerable Daily Intake (TDI), which is the amount of BPA a consumer (including babies and infants) can safely ingest without harm over a whole lifetime. The TDI was set by applying a safety factor of 100 to the No-Observed-Adverse-Effect-Level determined from studies on laboratory animals.

- A consumer would have to ingest more than 500 pounds of food and beverages in contact with BPA every day for a lifetime to exceed the TDI set by EFSA
- A 22 pound infant would have to drink more than 423 4 oz bottles per day to exceed the TDI

2. Products Made with BPA Contribute to the Health and Safety of Americans

- Epoxy resins are used as a protective coating in most metal food and beverage containers to help prevent corrosion and contamination, avoid food spoilage and provide a shelf life of two years or more.
 - Canned infant formula is provided to >8 million low-income women, infants and children at nutritional risk under the federal Special Nutrition Program for Women, Infants and Children (WIC)
- Shatter-resistant polycarbonate plastic made with BPA can be found in many products that contribute to health and safety:
 - Plastic bottles and cups without the risk of cuts from broken and chipped glass
 - Sports safety glasses (polycarbonate lenses are recommended by the American Academy of Ophthalmology)
 - Helmets
 - Sports safety equipment, such as face shields and face guards
 - Life-saving medical devices such as incubators and kidney dialysis machines
 - Blast and bullet resistant shielding to protect government officials, police, prison officials, military personnel, as well as bank tellers and convenience store clerks
- Polycarbonate is used to make lightweight products such as automotive parts that save energy.

3. BPA Makes an Important Contribution to U.S. Economy (2007 data)

- ~1,400 BPA and derivative plants operating in the U.S. – nearly all states represented – with an investment value of \$6 billion.
- >39,000 workers employed *directly* in chemical processing and plastic/resin facilities and downstream fabrication facilities.
- An additional 64,700 workers are employed *indirectly*. These individuals are employed in the wide network of supplier industries that provide goods and services (raw materials, utilities, capital goods, services) to the BPA industry.
- \$6.1 billion in total wages.
- Taxes – federal/state/local paid by the 39,000 workers – over \$1.3 billion + \$894 million in Social Security and Medicare.



GOVERNMENT AND INDEPENDENT SCIENTIFIC ASSESSMENTS

United States

- **U.S. Food and Drug Administration (FDA)** – In August 2008, FDA released a draft safety assessment of BPA in food-contact products (e.g., baby bottles, water bottles, food containers). The assessment was conducted by a cross-agency task force of FDA scientists and included data and information from recent government reviews of BPA, from non-governmental sources and the scientific literature. In particular, the findings of the National Toxicology program were incorporated into FDA's analysis. Overall, FDA concluded: *"an adequate margin of safety exists for BPA at current levels of exposure from food contact uses, for infants and adults."*

FDA continues to review BPA based on peer review comments from its Science Board. In February 2009, FDA stated *"With regard to BPA generally, based on all available evidence, the consensus of regulatory agencies in the United States, Canada, Europe and Japan is that the current levels of exposure to BPA through food packaging do not pose an immediate health risk to the general population, including infants and young children."*

- In October 2008, an **expert scientific panel**, convened by **Gradient Corporation**, published the results of its weight-of-the-evidence evaluation of low-dose reproductive and developmental effects of BPA. This evaluation is the third in a series that began with an evaluation, published in 2004, by an independent panel of scientific experts organized by the **Harvard Center for Risk Analysis**. Based on its review of scientific literature available through July 2008, the panel concluded: *"The weight of evidence does not support the hypothesis that low oral doses of BPA adversely affect human reproductive and developmental health."*
- **U.S. National Toxicology Program (NTP)** – The September 2008 NTP final report on the potential for BPA to affect human reproduction or development found no direct evidence for health effects in people. It also confirmed that human exposure to BPA is very low.

On a standard five-level scale ranging from 'serious concern' to 'negligible concern,' NTP reported no concerns for any age group at the top two levels and only negligible concern for adults. Based on what NTP characterized as limited and inconclusive evidence from laboratory animal studies, NTP expressed 'some concern' regarding effects on the brain, behavior, and the prostate gland but noted that additional research is needed to better understand whether these findings are of any human health significance. The NTP report is designed to serve as a resource to regulatory agencies and has specifically been considered in FDA's ongoing safety assessment.

- **California Proposition 65** – In July 2009 a panel of independent scientific experts convened by the California EPA's Office of Environmental Health Hazard Assessment unanimously concluded that bisphenol A should not be listed as a reproductive or developmental toxicant under California's Proposition 65 law. That law can require warnings when listed substances are present in consumer products. The panel's decision was based on their own review of the scientific evidence on bisphenol A.
- **NSF International** (a not-for-profit public health and safety organization) – In February 2008, NSF published its comprehensive safety assessment of BPA and set a safe intake level for BPA in drinking water. That level is comparable to the level established by the European Food Safety Authority for BPA in food. The assessment was led by Dr. Calvin Willhite, a respected scientist with the California Department of Toxic Substances Control.

Canada

- **Health Canada** – In October 2008, the Canadian government announced the conclusion of its screening risk assessment stating: *"The current research tells us the general public need not be concerned. In general, most Canadians are exposed to very low levels of bisphenol A, therefore, it does not pose a health risk."*

With respect to infants under 18 months, it said "[s]cience tells us that exposure levels are below those that could cause health effects; however, due to the uncertainty raised in some studies relating to the potential effects of low levels of bisphenol A, the Government of Canada is taking action to enhance the protection of infants and young children." Health Canada announced it will move forward with achieving the lowest reasonably achievable levels

of BPA in infant formula and a regulation to ban polycarbonate baby bottles, noting that the proposed ban applies only to baby bottles and not to polycarbonate bottles, tableware and food containers. A ban has not yet taken effect.

In July 2009, Health Canada released several reports with new data on bisphenol A in bottled water, baby food and infant formula. According to Health Canada, these new data confirm Health Canada's previous conclusion that "the current dietary exposure to BPA through food packaging is not expected to pose a health risk to the general population, including infants and children."

Europe

- **European Food Safety Authority (EFSA)** – In January 2007, EFSA released a comprehensive scientific assessment of BPA that was conducted by a panel of independent scientific experts from throughout the European Union. The panel increased by a factor of five the safe intake level for BPA (known as the Tolerable Daily Intake or TDI) that was established in 2002, based on the panel's view that recent data provided more certainty about the safety of BPA.

In July and October 2008, EFSA updated its 2007 assessment of BPA. EFSA reconfirmed its position that BPA-based polycarbonate and epoxy food contact products are safe for their intended uses. These updates examined recent data and concluded that newborns are able to metabolize. EFSA concluded that the TDI "*provides a sufficient margin of safety for the protection of the consumer, including fetuses and newborns.*"

- The **French Food Safety Authority (AFSSA, November 2008)**, the **Danish Environmental Protection Agency (October 2008)**, the **German Federal Institute for Risk Assessment (BfR, September 2008)**, the **Dutch Food and Consumer Product Safety Agency (VWA, November 2008)**, and the **Swiss Federal Office of Public Health (BAG/OFSP, February 2009)** have all re-evaluated BPA in light of recent studies and government decisions; **all conclude that BPA is safe for use in food contact applications.**
- *The French Minister of Health (March 31, 2009) questioned the Canadian government's use of the precautionary principle and stated: "Precautionary measures should only be applied in the absence of reliable studies confirming the safety of Bisphenol A. In fact, reliable studies do exist in accordance with the present science on the safety... The Canadian authorities decided to prohibit Bisphenol- A as a result of pressure from public opinion rather than on the basis of any serious scientific evidence... The principle of precautionary measures is based on reason and never on emotion."*
- **European Union** – In June 2008, an updated comprehensive **European Commission** risk assessment report confirmed low risk of BPA to human health, including use of polycarbonate plastic and epoxy resins in consumer products. The update takes into account the latest scientific studies available (through 2007) and completes a comprehensive assessment undertaken on BPA over 10 years. Based on this report, no bans or restrictions have been proposed.

All tests required by REACH to assess risk to human health have been completed. All of that test data, plus hundreds of other studies, were reviewed by the European Chemicals Bureau in the EU Risk Assessment. The conclusion of the EU Risk Assessment is that bisphenol A does not pose a risk to the general public from all current sources of exposure.

Japan

- **Japanese National Institute of Advanced Industrial Science and Technology** (affiliated with the Japanese Ministry of Economy, Trade and Industry) – In November 2005, a comprehensive report confirmed no risk of BPA to human health, including infants and children, and noted that no bans or restrictions are needed.
- **Japanese Ministry of Environment** – In 2005, based on its own comprehensive testing, concluded that there were no clear endocrine disrupting effects found at low doses and that no regulatory action is required to manage risks.

Australia and New Zealand

- **Food Standards Australia New Zealand (FSANZ** - an independent statutory agency responsible for setting food standards in the two countries) - On March 19, 2009 FSANZ reaffirmed the safety of BPA and stated: "*FSANZ has assessed the risk to infants from exposure to BPA and concurred with the conclusions reached by the US FDA and the EFSA that the levels of exposure are very low and do not pose a significant health risk.*"

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Questions & Answers

FDA UPDATE ON SAFETY OF BPA JAN. 15, 2010

Q. What did the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) recently say about BPA?

A. In an update announced in January 2010, the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) made it clear that BPA "is not proven to harm children or adults..." This is consistent with a draft assessment issued by FDA in 2008, and the scientific conclusions of many other government regulatory agencies around the world.

FDA confirmed that studies using standardized toxicity tests continue to support the safety of BPA. FDA noted some studies, using novel approaches to testing for subtle effects, had raised questions and the agency stated it would conduct additional scientific research to answer these key questions and clarify uncertainties. Although the agency noted "some concern," it did not take regulatory action or impose restrictions on the use of BPA as a part of this review. FDA chose to proceed with additional research, indicating the results of that research will be available in about 18-24 months.

FDA did not recommend avoiding the use of polycarbonate products in food contact products. HHS, which oversees FDA, provided consumers with precautionary steps they can take to reduce exposure to BPA. For example, parents should not put very hot or boiling liquid that is intended for a baby's consumption in containers that contain BPA.

Q. Does FDA's announcement mean that BPA is not safe in polycarbonate baby bottles or sippy cups?

A. *The Los Angeles Times* reported that the FDA principal deputy commissioner stated that for the present "FDA does support the use of baby bottles with BPA." He also stated, "If we thought it was unsafe, we would be taking strong regulatory action," as reported by *The New York Times*.

FDA has not said that BPA is unsafe and has not advised parents to stop using polycarbonate baby bottles or sippy cups. HHS provided consumers with precautionary steps they can take to reduce exposure to BPA, if they so wish. However, consumers should be reassured that 10 regulatory agencies from around the world continue to reaffirm the safety of BPA based on current science.

Q. What does FDA mean by the comment that it has “some concern” about BPA?

A. As reported in *The Los Angeles Times*, the FDA Commissioner explained, “We have some concern meaning in part that we need to know more.” As part of its update, FDA outlined research, some of which is already under way, that is aimed at addressing certain questions about BPA.

However, it is important to note that while FDA gathers additional scientific information on BPA, it did not take regulatory action or impose restrictions on the use of BPA as a part of this review. FDA made it clear that BPA “is not proven to harm children or adults.” This recent statement is consistent with conclusions of numerous other government regulatory agencies around the world.

Q. Does BPA bioaccumulate in people?

A. No. Much is known about how BPA is metabolized (processed) by the human body. Scientific research shows that in humans BPA is quickly metabolized in the intestines and liver and is quickly eliminated from the body. It does not accumulate in blood or tissues. When it is ingested through contact with food, it is rapidly converted into a metabolite (BPA-glucuronide) that has no known biological activity.

Q. Are infants particularly sensitive to BPA?

A. A recent study with premature infants by researchers at Harvard and the Centers for Disease Control and Prevention demonstrated that premature infants have ample capacity and capability to metabolize and eliminate BPA.

HHS noted that for liquid infant formula, “the benefits of good nutrition from liquid infant formula sold in cans far outweigh the potential risk of exposure to a small amount of BPA. As a result, HHS does not advise against the use of liquid infant formula in cans.”

Q. Why is BPA used in food containers?

A. BPA is used to make clear, durable and shatter-resistant plastic that provides a clear view of the food or beverage in a durable and temperature-resistant container. BPA is also used to make epoxy resins, which are used as durable linings in cans that help protect the integrity and the safety of the canned food. Approved by FDA for safe use in food containers for decades, BPA is one of the most thoroughly tested chemicals in commerce today.

Q. Has HHS advised against using baby bottles made with BPA?

A. No. HHS has provided guidance for how consumers can reduce exposures if they so wish, but has not advised that consumers need to discontinue use of baby bottles made with BPA.

Bear in mind, HHS indicated that most major manufacturers no longer use BPA in baby bottles. HHS advises parents to throw away plastic baby bottles and infant

feeding cups that are scratched, primarily to reduce the risk of bacterial growth. Similarly, HHS recommends that parents avoid putting boiling or very hot liquids into bottles made with BPA in order to minimize exposures.

Q. Is polycarbonate plastic safe for use in non-food contact applications, including children's toys?

A. Regulatory agencies around the world charged with reviewing the science on BPA have consistently and repeatedly answered, "yes." While not widely used in toys, polycarbonate plastic is used in sports safety equipment such as bicycle helmets for its shatter-resistant properties. HHS stated that plastic children's toys need not be thrown away and, for pacifiers, the "part of the pacifier that a child puts in his or her mouth is made from latex or silicone and does not contain BPA. In some pacifiers, the hard plastic shield designed to prevent swallowing might contain BPA; however, the only exposure would come from the child mouthing the shield, and the transfer of BPA is negligible."

Q. Why is further research being conducted?

A. Questions about how to interpret certain animal research and its implications for human health led FDA to conduct additional research to more fully evaluate and understand potential health effects of BPA exposure. According to the agency, results are expected in 18-24 months.

Q. What have other regulatory agencies said about BPA?

A. Ten regulatory bodies around the world have assessed the science on BPA and have determined that BPA is safe for use in food contact products.

- European Food Safety Authority (January 2007, July 2008, October 2008)
- European Commission Risk Assessment (June 2008)
- Swiss Federal Office of Public Health (February 2009)
- French Food Safety Authority (November 2008)
- Dutch Food and Consumer Product Safety Authority (November 2008)
- Danish Environmental Protection Agency (October 2008)
- German Federal Institute for Risk Assessment (September 2008)
- Food Standards Australia and New Zealand (March 2009, January 2010)
- Japanese National Institute of Advanced Industrial Science and Technology (November 2005)
- Health Canada (October 2008, July 2009) concluded that exposure is below levels that pose a risk, but as a precautionary measure proposed to ban polycarbonate baby bottles in Canada.

Q. Where can I get further information?

A. Consumers can get more information on BPA at the following Web sites:

- www.americanchemistry.com
- www.factsaboutBPA.org
- www.hhs.gov/safety/bpa
- www.fda.gov/NewsEvents/PublicHealthFocus

